Do You Know Your QMM?

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Don't panic if you aren't familiar with the above acronym, which stands for *Quality Management Maturity.*

Start Preparing

Actually, some readers may be familiar with QMM. "it's a hot topic." It is defined QMM as "*the state attained by having consistent, reliable, and robust business processes to achieve Quality objectives and to promote continual improvement*." A mouthful, perhaps. It is most interesting in the elements that *quality culture and quality metrics* might play in this realm.

QMM began when the FDA was tasked by the U.S. Congress in 2019 to evaluate why drug shortages have been increasing. One proposal that emerged from FDA activites is to establish a *QMM rating* for manufacturing facilities. The overall theory here is that the "maturity" of a facility is vital to increased reliability and quality controls. A well-matured facility (see below) is less likely to have quality defects or other manufacturing issues that could precipitate drug shortages.

If the ball keeps rolling, "we can imagine within the decade that CDMO manufacturing sites will have this QMM rating." "Sponsors will be able to better focus on contracting with more established and experienced manufacturing sites, those owning a track record of going above and beyond the competition."

More Mature

Yes, age has something to do with assessing a facility is "mature." Acquiring a QMM score and accompanying report, would allow for a fuller assessment of a facility than is possible currently. Among other items, information would include:

- proven manufacturing capabilities
- compliance and inspection history
- batch-release statistics
- material recalls
- quality challenges

Groups such as PDA and DIA are working with the FDA to home in on all the different elements to include in a QMM rating – including *algorithms for quality*. "There's no formalized guidance document yet, but QMM is indeed being actively shaped for the future,". (There have been, though, pilot studies, FDA requests for comments, and QMM white papers.)

A future with QMM

I'm a CDMO with a number of manufacturing facilities. I can invite the FDA to inspect some (or all) of those locations, review the longevity of the facility and track record, and provide us a QMM rating per facility. "That is an application, "but I'd rather avoid the word *inspect*." "It's not an inspection. I envision it as the FDA – or a third party approved by the FDA – having personnel go onsite and ask particular questions that feed into a QMM rating or score.

"Being discussed now is a *mix of qualitative and quantitative analysis*." This one from the sponsor's standpoint. "*Imagine I'm the CEO of Pharmaceuticals (a fictitious virtual biopharma company), interested in three CDMOs. I go to the CDMOs and ask if they have a QMM rating from the FDA. If they do, I'll excitedly ask to see it. By*

evaluating and comparing these ratings, I'll have a deeper understanding of the maturity of the sites and how reliably they deliver."

And pay attention here: *Pharmaceuticals might decide to obtain its own QMM rating*.
"Drug sponsors could ask for an independent QMM assessment report to highlight certain areas of our business, or for example, to help us identify quality systems we need to improve on – utilize the QMM system as another way to improve our operations."

Who Reviews What?
On to the million-facility question:
How will the FDA handle this additive resource burden? Well documented is how the agency is already behind on inspecting facilities – particularly those situated abroad. How would the FDA get to all of these sites requesting a QMM and receive the additional funding to accomplish this? "That's definitely an area of concern with the Agency,".

"I read different budget proposals the FDA publishes, in terms of how many staff members they are trying to hire for inspectors and investigation. Like many of us, I am sure they are having difficulties hiring professionals. "It's a battle the agency will have to continue to move forward on."

That battle is why the FDA is evaluating whether third parties could perform QMM assessments. If the FDA does decide to go down that route, there would have to be a serious vetting process, with applied standards and requirements for these contractors. Back to the facilities themselves, some pilot studies for the QMM rating, where particular biopharma companies have agreed to be assessed in regards to an in-the-works QMM rating system.

Finally, I imagine some readers lean skeptical of this added layer of assessment "bureaucracy," and whether a rating system would actually accomplish its objective – minimize and mitigate drug shortages due to manufacturer challenges. Others of you, though, might be eager to have such a tool to help in locating and assessing the most reliable and high-quality CDMOs. And in having your own facilities assigned and assigned a QMM.

CDMOs, for their part, may have differing opinions on this – certainly many questions to be answered before welcoming QMM ratings. In fact, these are the comments most industry professionals are concerned with about the QMM program .For now, let's be grateful the FDA has industry organizations and some biopharma collaborators, and professionals, considering how to alleviate drug shortages caused by manufacturing issues.So, what's your CDMO's QMM?

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